Increased respect for patient's autonomy: the good and the bad side

Informed consent

F. Gerstenbrand

37th International Danube Symposium for Neurological Sciences and Continuing Education
Ljubljana, October 8th, 2005

Occidental Ethics

Western ethical thinking, "Christian Ethics"

- Socrates, Plato, Aristoteles	Greek philosophy: moral virtue values are natural rather than conventional ethics as science
- Saint Augustinus, Thomas Aquinas	Incorporation of Greek ethics in Christian religion Attainment of happiness God given natural order
- Immanuel Kant	Categorical imperative: the individual shall always act in a way, that his action can be regarded as general law
- Modern ethics	Different schools: - Value ethics - existentialistic ethics - American bioethics - Marxist ethics - theological ethics

Definition of ethics

- **Ethics:** Part of philosophy dealing with morality
- **Moral** is search for an inner standard
- **Kant' s Categorical Imperative:**
  The individual shall always act in a way that his action can be regarded as general law

Non-Western Ethics

partly religious based

- Ethical rules in Buddhism
  end of being - rebirth, Nirvana
- Ethical rules in Confucianism
  appreciation of well being of the community above the well being of the individual
- Ethical rules in Mosaic religion
- Ethical rules in Islamic religion
- Ethical rules of natural religions
  Massai religion, African religious communities, Shamanism

Ethics

- Altruism
- Sense of Honour
- Justness
- Respect for others
- Solidarity
- Ability to forgive

Hippocratic Oath

Obligation to heal
Not do anything to harm the patient
No continuation of therapy in untreatable disease
No therapy in advanced physical and mental destruction
No continuation of life prolongation for hours or days
No prolongation of suffering during dying
Not to tell anyone the details of patients
No admitting of lethal poison, even as advice

Will to respect the teacher like own parents, sharing one's life support of successors of the teacher, treated like own brothers
Medical teaching to own sons and the sons of the teacher or to pupils bound on physicians rules and oath

Ethics in medicine I

... is necessary for each human being :

- any preventive, diagnostic and/or therapeutic medical intervention
- scientific research (basic research, clinical studies) according to
  - ICH-GCP (Good Clinical Practice)
  - GMP (Good manufacturing practice)
  - Clinical trials for new diagnostic and therapeutic methods

Declaration on Bioethics and Human Rights

Universal Draft, Paris, 24.6.2005

UNO

UNESCO

- SHS: Social and Human Sciences
- BIOETHICS

Ethics in medicine II

... based on:

- Declaration of Helsinki (with amendments)
- Declaration on Bioethics and Human Rights, Paris, 2005
- Domestic and international law in confirmity with human rights law

Declaration on Bioethics and Human Rights

Universal Draft, Paris, 24.6.2005

Person's identity includes

- biological dimension
- psychological dimension
- social dimension
- cultural dimension
- spiritual dimension

WMA Declaration of Helsinki, 1964

Medical Research Involving Human Subjects
Ethical Principles

- Medical progress is based on research, which ultimately must rest in part on experimentation involving human subjects
- In medical research on human subjects considerations related to the well-being of the human subject should take precedence over the interest of science and society
- International Code of Medical Ethics : A physician shall act only in the patient 's interest when providing medical care, which might have the effect of weakening the physical and mental condition of the patient
- Ethical Principles to provide guidance for physicians and other participants in medical research involving human subjects including identifiable material or identifiable data

Bioethical principles

Medical conduct, physicians obligations
(Belmont Criteria, 1979)

- Autonomy of the patient
- Beneficience
- Nonmalefficiency
- Justice
- Trust

Patient-Doctor Relationship

- Expectation of personal attention
- Trust
- Individualized treatment
- Best available and best care/practice
- Best benefit to risk/ratio
- Treatment according to the 'state of the art'
- Informed consent

- Evidence Based Medicine? Cochrane Library?

Informed consent
patient able to consent

- Content of written information
  - Aims
  - Expected benefits for the subjects and/or others
  - References treatment/placebo
  - Risks and inconveniences
  - If applicable, an explanation of alternative standard medical therapy
- Consent must be documented by either the subject's dated signature or by the signature of an independent witness
- The signature confirms that the consent is based on information that has been understood and that the subject has voluntary chosen to participate

Informed consent
in daily practice

... is based on:

- Declaration of Helsinki, 1964 (with amendments)
- Declaration on Bioethics and Human Rights, Paris, 2005
- Domestic and international law in conformity with human rights law

Human research and subject protection
basic rules

- Informed consent to the patient
- Education and training of investigator
- Appropriate training for investigator in bioethics and other issues related to research involving human subject
- Improved monitoring
- Conflicts of interests
- Civil monetary penalty for violation of research (investigator, research institute)

Declaration of Paris, 2005
Article 6a - Consent

Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.

The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

Clinical Trial in Medicine
Basic Principles

- Patient changes to an examination object
- Physician changes to investigator

- Protocol of the trial, prepared in an exact form
- Protocol submission to the Independent Ethics Committee (IEC)
- Sponsor: industry, academic
- Investigator with exact training

- Procedure according to the principles of ICH – GCP
- Exact monitoring during the trial
- Audits and inspections procedure
- Strict anonymity of the trial results
- Careful archive of the results

Declaration of Helsinki
Definition of "Informed consent" (clinical trial)

The voluntary confirmation of a subject's willingness to participate in a particular trial, and the documentation thereof. This confirmation should only be sought after information has been given about the trial including an explanation of its objectives, potential benefits and risks and inconveniences, and of the subject's rights and responsibilities in accordance with the current revision of the Declaration of Helsinki.

Good clinical practice (GCP) for trial on medical products
International Conference of Harmonization (ICH-GCP)

- **Protection of trial subject**
  - Ethics Committee
  - Informed consent (voluntary, detailed information)
  - Insurance
- **Responsibility of the**
  - Sponsor
  - Investigator
  - Monitor
- **Data handling**
  - Investigator
  - Sponsor/monitor
  - Safety reporting of serious adverse events (SAE)
  - Archive of data
- **Statistics** (experimental design, randomization, statistical analyse)
- **Quality assurance / Quality management**

Informed consent in clinical trial

... is based on:

- Principles of GCP and GMP
- Principles, regulations and guidelines of federal or other responsible organisations
  - the European Council/European Community
  - ICH (International Conference of Harmonization)
  - FDA (Food and Drug Administration)

Bad Clinical Practice (1)

- Malevolence
  - Sabotage of research, theft of data
- Fraud
  - „Improvement" of data/results
  - „Arbitrary" correction to meet inclusion criteria
  - Totally or partially fabricated cases
- Violation of ethical principles
  - Inadequate consequence
  - Selection of subjects (inadequate exclusion of „high risk group")
  - Dangerous or disturbing invasive procedures
  - Distress by contact of study
  - Dangerous treatment (inadequate safety information, withdrawal of the proved substance)
  - Insufficient confidentiality
  - Low insurance coverage

Principles of ICH-GCP for Clinical Trial

- In accordance with ethical principles
- Only if benefits justify the risks
- Rights, safety and well-being of trial subjects are most important
- Supported by adequate non-clinical and clinical information
- Scientifically sound with clear detailed protocol
- Compliance with protocol and after approval by ethics committee
- Physician responsible for medical care of subjects and medical decisions

Bad Clinical Practice (2)

- Protocol violations
  - Insufficient knowledge/understanding
  - Omissions (tests left out)
  - Errors involving
    - patient selection
    - evaluation
    - dates
    - treatment (dose, concomitant medication, allocation)
    - blindness
- Erroneous Values
  - Work overload
  - negligence
  - incompetence

Patients unable to consent

(temporary – permanently)

Neurology-Psychiatry

Basic legal prerequisite for every medical intervention:
„Informed consent" – better „valid consent"

Informed consent

clinical trial – incapable patient

- If the subject is incapable of giving personal consent (e.g. unconsciousness), the inclusion of such patients may be acceptable if
  - The EC (ethics committee) is, in principle, in agreement
  - Participation will promote the welfare and interest of the subject
  - If possible, written consent of a legally valid representative
- Consent in a non-therapeutic study always the legal representative always has to be informed
- Any information becoming available during the trial which might be of relevance for the subject must be made known to him

Protection of vulnerable persons

Inability to consent in routine medical practice
(Reduced capacity)
Specific laws, rules and regulations

- Children (parents and guardians as proxy depending on maturity of minors
- Patients with cognitive impairments
- Apallic patients/Vegetative State
- Patients with severe progressive or terminal disease
- Patients in intensive care

Informed consent generally

... is necessary for each human being (patient and healthy volunteer):

- any preventive, diagnostic and/or therapeutic medical intervention
- scientific research (basic research, clinical studies) according to
  - ICH-GCP (Good Clinical Practice)
  - GMP (Good manufacturing practice)
  - Clinical trial for new diagnostic and therapeutic methods

Patients not able to consent

- In clinical practice
  the treating and responsibility physician often is the true protector of the patient who is incapacitated
- In research
  Conflicting interest
  - Protecting the research subject
  - Advancing medical knowledge

Rights and responsibilities
Physician and patient

- The treating physician has the individual responsibility for his patient. Highest level of his education and training is essential and necessary.
- The treating physician is guided by ethical principles, medical guidelines, declaration, domestic and international law and human rights law.
- "New ethics in medical treatment" are created.
- The personal responsibility of the physician to his patient can't be replaced.
- Patient's right is to accept or to refuse the recommendation of a treatment program.
- Patient's right is to interrupt a running treatment program
- The physician's obligation is to inform the patient about the danger for his health to refuse or to interrupt a treatment program.

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Ljubljana: Neurological association: Society of Clinical Neurophysiology. 2005

SATURDAY, October 8

08.30–09.15 **The Danube Lecture**
Chairperson: B. Klun (Ljubljana, Slovenia)
V. V. Dolenc (Ljubljana, Slovenia):
Role of neurosurgery in neuroscience,
daily practice and research ..... N/A

09.15–11.15 **Ethical issues in neurology**
Local coordinator: J. Trontelj
Chairpersons: J. Trontelj (Ljubljana, Slovenia)
and F. Gerstenbrand (Vienna, Austria)
F. Gerstenbrand (Vienna, Austria):
Increased respect for patient's autonomy:
the good and the bad side ..... N/A
D. Neubauer (Ljubljana, Slovenia):
Dilemmas surrounding end-of life decisions
in paediatric and adult neurology 104
A. Grad (Ljubljana, Slovenia):
Do we have time for ethical issues in
neuro-intensive care unit? 105
D. Bartko (Ružomberok, Slovakia):
Brain death and/or end of person's life 106
J. Trontelj (Ljubljana, Slovenia): Permanent
vegetative state: end of person's life? 109
Questions and comments from the audience

11.15–11.30 *Coffee break*

11.30–13.30 **Polyneuropathies**
Local coordinator: T. Žgur
Chairpersons: T. Žgur (Ljubljana, Slovenia)
and W. Grisold (Vienna, Austria)
W. Grisold (Vienna, Austria):
Clinical approach to polyneuropathies 111
J. Zidar (Ljubljana, Slovenia):
Electromyographic diagnosis of
polyneuropathies 113
S. Apostolski (Belgrade, Serbia and
Montenegro): Immunology of
polyneuropathies – diagnostic applications .. 115

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BOOK OF ABSTRACTS

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